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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,155	05/14/2001	Stephen E. Allen	03109-033001	1126
26161	7590	06/16/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			THERKORN, ERNEST G	
			ART UNIT	PAPER NUMBER
			1723	
DATE MAILED: 06/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/855,155

Applicant(s)

ALLEN ET AL.

Examiner

Ernest G. Therkorn

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 8-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1-7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 102(B) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Frechet (U.S. Patent No. 5,334,310). The claims are considered to read on Frechet (U.S. Patent No. 5,334,310). However, if a difference exists between the claims and Frechet (U.S. Patent No. 5,334,310), it would reside in optimizing the elements of Frechet (U.S. Patent No. 5,334,310). It would have been obvious to optimize the elements of Frechet (U.S. Patent No. 5,334,310) to enhance separation.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frechet (U.S. Patent No. 5,334,310) in view of Hatch (U.S. Patent No. 6,238,565). At best, the claim differs from Frechet (U.S. Patent No. 5,334,310) in reciting the monolith is preformed. Hatch (U.S. Patent No. 6,238,565) (column 8, line 62-65) discloses that a monolith may be polymerized in situ within a tube or formed outside a tube and then inserted by any suitable means. It would have been obvious to use a preformed

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monolith in Frechet (U.S. Patent No. 5,334,310) because Hatch (U.S. Patent No. 6,238,565) (column 8, line 62-65) discloses that a monolith may be polymerized in situ within a tube or formed outside a tube and then inserted by any suitable means.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Leavesley (U.S. Patent No. 5,601,708), McDonald (U.S. Patent No. 4,250,035), and Conroy (WO 97/43024) in view of either Frechet (U.S. Patent No. 5,334,310) or Hatch (U.S. Patent No. 6,238,565). At best, the claims differ from each of Leavesley (U.S. Patent No. 5,601,708), McDonald (U.S. Patent No. 4,250,035), and Conroy (WO 97/43024) in reciting use of a monolith inside the vessel. Frechet (U.S. Patent No. 5,334,310) (column 3, lines 51-57) discloses that monoliths have the advantages of compactness, a very high permeability ratio, and very high column efficiency relative to a packed column. Hatch (U.S. Patent No. 6,238,565) (column 4, lines 15-30) discloses that monoliths have the advantages of ease of manufacture, lack of bead shifting, and at least 58% better resolution relative to a packed column. It would have been obvious to use a monolith in each of Leavesley (U.S. Patent No. 5,601,708), McDonald (U.S. Patent No. 4,250,035), and Conroy (WO 97/43024) either because Frechet (U.S. Patent No. 5,334,310) (column 3, lines 51-57) discloses that monoliths have the advantages of compactness, a very high permeability ratio, and very high column efficiency relative to a packed column or because Hatch (U.S. Patent No. 6,238,565) (column 4, lines 15-30) discloses that monoliths have the advantages of ease of manufacture, lack of bead shifting, and at least 58% better resolution relative to a packed column.

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Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over each of Leavesley (U.S. Patent No. 5,601,708), McDonald (U.S. Patent No. 4,250,035), and Conroy (WO 97/43024) in view of either Frechet (U.S. Patent No. 5,334,310) or Hatch (U.S. Patent No. 6,238,565) as applied to claims 1-7 above, and further in view of Hatch (U.S. Patent No. 6,238,565). At best, the claim differs from each of Leavesley (U.S. Patent No. 5,601,708), McDonald (U.S. Patent No. 4,250,035), and Conroy (WO 97/43024) in view of either Frechet (U.S. Patent No. 5,334,310) or Hatch (U.S. Patent No. 6,238,565) in reciting the monolith is preformed. Hatch (U.S. Patent No. 6,238,565) (column 8, line 62-65) discloses that a monolith may be polymerized in situ within a tube or formed outside a tube and then inserted by any suitable means. It would have been obvious to use a preformed monolith in each of Leavesley (U.S. Patent No. 5,601,708), McDonald (U.S. Patent No. 4,250,035), and Conroy (WO 97/43024) in view of either Frechet (U.S. Patent No. 5,334,310) or Hatch (U.S. Patent No. 6,238,565) because Hatch (U.S. Patent No. 6,238,565) (column 8, line 62-65) discloses that a monolith may be polymerized in situ within a tube or formed outside a tube and then inserted by any suitable means.

The remarks urge patentability based upon the allegation that Frechet (U.S. Patent No. 5,334,310) does not disclose a monolith in a flexible tube. However, Frechet (U.S. Patent No. 5,334,310) discloses a monolith on column 3, lines 9-13 and a tube with flexibility on column 4, lines 29-30. In addition, use of a monolith in a flexible tube is disclosed to be prior art in Frechet (U.S. Patent No. 5,334,310) on column 2, lines 43-

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52. An example of a monolith in a flexible tube is disclosed in Comparative Example A on column 12, lines 6-19.

The remarks urge that column 4, lines 29-30 of Frechet (U.S. Patent No. 5,334,310) is a teaching away from flexibility. However, teaching "Although the tube may have a limited amount of flexibility, it must be substantially rigid so that there is substantially no change in volume of the tube during the polymerization reaction" is not considered to be a teaching away. The teaching is considered to be guidance for how to make a flexible tube.

The remarks urge that Frechet (U.S. Patent No. 5,334,310) may have some mechanism to prevent his flexible tube from being deformable. However, no such structure is disclosed. Applicants' disclosed "flexible wall that is deformable by externally applied force so as to reduce a volume with said vessel" is the same as Frechet (U.S. Patent No. 5,334,310), namely, a plastic tube.

The remarks urge that Frechet (U.S. Patent No. 5,334,310)'s Comparative Example A is inoperative. However, a fair reading of Frechet (U.S. Patent No. 5,334,310)'s Comparative Example A and the immediately following claim 1 would indicate that good results would have been achieved if pores having diameters greater than about 600 nm were present.

The remarks appear to urge that there is no motivation to combine each of Leavesley (U.S. Patent No. 5,601,708), McDonald (U.S. Patent No. 4,250,035), and Conroy (WO 97/43024) with either Frechet (U.S. Patent No. 5,334,310) or Hatch (U.S. Patent No. 6,238,565). However, Frechet (U.S. Patent No. 5,334,310) (column 3, lines

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51-57) discloses that monoliths have the advantages of compactness, a very high permeability ratio, and very high column efficiency relative to a packed column. Hatch (U.S. Patent No. 6,238,565) (column 4, lines 15-30) discloses that monoliths have the advantages of ease of manufacture, lack of bead shifting, and at least 58% better resolution relative to a packed column. Motivation exists to use a monolith in each of Leavesley (U.S. Patent No. 5,601,708), McDonald (U.S. Patent No. 4,250,035), and Conroy (WO 97/43024) either because Frechet (U.S. Patent No. 5,334,310) (column 3, lines 51-57) discloses that monoliths have the advantages of compactness, a very high permeability ratio, and very high column efficiency relative to a packed column or because Hatch (U.S. Patent No. 6,238,565) (column 4, lines 15-30) discloses that monoliths have the advantages of ease of manufacture, lack of bead shifting, and at least 58% better resolution relative to a packed column.

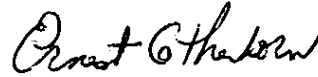
Any inquiry concerning this communication should be directed to E. Therkorn at telephone number (571) 272-1149. The official fax number is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



**Ernest G. Therkorn**  
**Primary Examiner**  
**Art Unit 1723**

EGT

June 10, 2004